

January 26, 2007

The Honorable Henry Waxman  
United States House of Representatives  
2204 Rayburn House Office Building  
Washington, DC 20515

Dear Congressman Waxman:

Congratulations on your introduction of legislation to provide a system for bringing safe generic biologic medicines to market. Consumers Union, the independent, non-profit publisher of Consumer Reports, strongly supports your effort to break the logjam of indecision and inaction at the Food and Drug Administration and clarify how drug manufacturers can proceed to bring safe biogenerics to consumers. While the European Union has been moving to provide guidance and direction to its biogeneric industry, the FDA is obviously waiting for Congressional guidance. Your bill fills this key role.

Biogenerics are clearly the future of pharmacy and hold the promise of truly miraculous advances in the health of mankind. While about 125 products have been approved to date, there are reportedly over 400 biologics in the research pipeline to treat more than 100 different diseases. With nearly 1500 biotechnology companies in the United States, it is clear that this is a huge growth area.

The problem for consumers is that these drugs are more expensive than older generations of drugs to manufacture and the price of many of these drugs is a quantum leap above older drug prices. It is common for a biologic to cost several thousand dollars a month with some treatments costing \$60,000 to \$100,000 a year, and with one colorectal cancer treatment costing about

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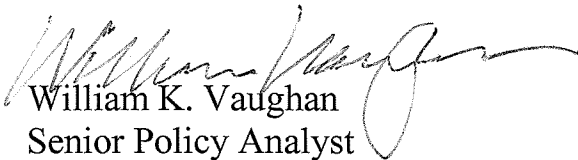
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\$250,000 per person. Because of the failure to devise a system for the consideration of complex biologics, there is no end in sight to monopoly pricing of biologics, even though many of these products become extremely profitable. Your bill would finally allow generics that are comparable or interchangeable to enter the market and provide some competition after a reasonable period of patent protection. It is not exaggeration to say that over the coming years, this legislation will save American consumers billions and billions of dollars and will make a major difference in the future cost of the Medicare drug benefit and the Federal-State Medicaid programs.

We look forward to working with you in enacting this legislation in the 110<sup>th</sup> Congress. Congratulations again for your outstanding leadership in this sector.

Sincerely,



William K. Vaughan  
Senior Policy Analyst